IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

LUZ LECHUGA,	)	
	)	
PLAINTIFF,	)	
	)	Civil Action No: _____
vs.	)	
	)	
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and ELI LILLY & COMPANY,	)	COMPLAINT
	)	JURY TRIAL DEMANDED
DEFENDANTS.	)	
_____	)	

COMPLAINT AND JURY DEMAND

Plaintiff, Luz Lechuga ("Plaintiff"), by and through the undersigned counsel hereby submits this Complaint and Jury Demand against Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Pharma GMBH & Co. KG, Boehringer Ingelheim International GMBH, and Eli Lilly & Company ("Defendants"), for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from the injuries to Plaintiff Luz Lechuga as a result of her injuries suffered as a direct and proximate result of taking the prescription drug JARDIANCE® (also known as empagliflozin). In support of her Complaint, Plaintiff alleges the following:

INTRODUCTION

1. Defendants, directly or through their agents, apparent agents, servants or employees, designed, manufactured, marketed, advertised, licensed, distributed, and/or sold JARDIANCE for the treatment of diabetes.

2. Defendants concealed, and continue to conceal, their knowledge of JARDIANCE's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

3. As a result of the defective nature of JARDIANCE, persons who were prescribed and ingested JARDIANCE, including Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including diabetic ketoacidosis, stroke, heart attack and severe kidney damage.

4. After beginning treatment with JARDIANCE, and as a direct and proximate result of Defendants' actions and inaction, Plaintiff Luz Lechuga developed diabetic ketoacidosis. Plaintiff's ingestion of the defective and unreasonably dangerous drug JARDIANCE has caused and will continue to cause injury and damage to Plaintiff.

5. This is an action for product liability, design defect, failure to warn, negligence, fraud, misrepresentation, and breach of warranties against Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Pharma GMBH & Co. KG, Boehringer Ingelheim International GMBH, and Eli Lilly & Company.

6. Plaintiff Luz Lechuga brings this action for personal injuries suffered as a proximate result of being prescribed and ingesting JARDIANCE. Plaintiff accordingly seeks compensatory and punitive damages, monetary restitution, and all other available remedies as a result of injuries caused by JARDIANCE.

PARTIES

7. Plaintiff, Luz Lechuga, is a citizen and resident of El Paso, El Paso County, Texas.

8. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer US") is a Delaware corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Boehringer US has conducted business and derived

substantial revenue from within the State of Texas, and Boehringer US expected or should have expected its acts to have consequences within the State of Texas.

9. Defendant Boehringer Ingelheim Pharma GmbH & Co. KG ("Boehringer Pharma") is a foreign corporation with its principal place of business located at Boehringer Ingelheim Pharma GmbH & Co. KG, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany. Boehringer Pharma has transacted and conducted business within the State of Texas. Boehringer Pharma has derived substantial revenue from goods and products disseminated and used in the State of Texas, and Boehringer Pharma expected or should have expected its acts to have consequences within the State of Texas.

10. Defendant Boehringer Ingelheim International GmbH ("Boehringer International") is a foreign corporation with its principal place of business located at Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein, Germany. Boehringer International has transacted and conducted business within the State of Texas. Boehringer International has derived substantial revenue from goods and products disseminated and used in the State of Texas, and Boehringer International expected or should have expected its acts to have consequences within the State of Texas.

11. Defendant Eli Lilly and Company ("Lilly") is an Indiana corporation with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly has transacted and conducted business within the State of Texas. Lilly has derived substantial revenue from goods and products disseminated and used in the State of Texas, and Lilly expected or should have expected its acts to have consequences within the State of Texas.

JURISDICTION AND VENUE

12. This Court has jurisdiction over Defendants in this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendants and because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because, among other reasons, Defendants have significant contacts with this district by virtue of doing business within this judicial district.

13. At all times relevant to this action, Defendants, either directly or indirectly, engaged in the business of marketing, promoting, distributing, and selling prescription drug products, including JARDIANCE, within the State of Texas, with a reasonable expectation that the product would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

14. At all times relevant to this action, Defendants engaged in disseminating inaccurate, false, and misleading information about JARDIANCE to health care professionals in the State of Texas, with a reasonable expectation that such information would be used and relied upon by health care professionals throughout the State of Texas.

15. Defendants engaged in substantial business activities in the State of Texas. At all relevant times, Defendants transacted, solicited, and conducted business in the State of Texas through their employees, agents and/or sales representatives and derived substantial revenue from such business in Texas.

16. Further, Defendants committed torts in whole or in part against Plaintiff in the State of Texas. As such, this Court has personal jurisdiction over all named Defendants.

17. Venue is proper within the Western District of Texas pursuant to 28 U.S.C. § 1391 because Plaintiff resides in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

FACTUAL BACKGROUND

18. At all times relevant Defendants, directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold the diabetes drug JARDIANCE.

19. Defendant Lilly indicates JARDIANCE revenue of $19.3 million from 2015. Additionally, for the first quarter of 2016 alone, Lilly recognized JARDIANCE revenue of $38.2 million.

20. In July 2014, Defendants submitted a New Drug Application to the United States Food and Drug Administration (FDA) for JARDIANCE.

21. In August 2014, the FDA approved Defendants' compound JARDIANCE (*empagliflozin*) for the treatment of Type II diabetes.

22. *Empagliflozin* is a member of the *gliflozin* class of pharmaceuticals, also known as sodium-glucose cotransporter 2 ("SGLT2") inhibitors, and is marketed in the United States by Defendants under the name JARDIANCE.

23. SGLT2 inhibitors, including JARDIANCE, primarily are used for treating type 2 diabetes.

24. SGLT2 inhibitors, including JARDIANCE, are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, excess glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease.

25. Though JARDIANCE is indicated for only improved glycemic control in type 2 adult diabetics, Defendants have marketed and continued to market JARDIANCE for off label purposes, including but not limited to weight loss, reduced blood pressure, and improved glycemic control in type 1 diabetics.

26. Since JARDIANCE's release, the FDA has received a significant number of reports of diabetic ketoacidosis among users of JARDIANCE.

27. An analysis of the FDA adverse event database shows that patients taking JARDIANCE are several times more likely to report diabetic ketoacidosis than those taking non-SGLT2 diabetes drugs to treat diabetes.

28. Despite Defendants' knowledge of the increased risk of severe injury among JARDIANCE users, Defendants did not warn patients but instead continued to defend JARDIANCE, mislead physicians and the public, and minimize unfavorable findings.

29. Consumers, including Plaintiff Luz Lechuga, who have used JARDIANCE for treatment of diabetes, have several alternative safer products available to treat the condition.

30. Defendants knew of the significant risk of diabetic ketoacidosis caused by ingestion of JARDIANCE. However, Defendants did not adequately and sufficiently warn consumers, including Plaintiff Luz Lechuga, or the medical community, of the severity of such risks.

31. To the contrary, Defendants conducted nationwide sales and marketing campaigns to promote the sale of JARDIANCE and willfully deceived Plaintiff, her health care professionals, the medical community, and the general public as to the health risks and consequences of the use of the JARDIANCE.

32. As a direct result, on or about July 24, 2015, Plaintiff began taking JARDIANCE per her doctor's instructions, primarily to treat diabetes.

33. Plaintiff ingested and used JARDIANCE as directed and on a foreseeable manner.

34. The JARDIANCE used by Plaintiff was provided to her in a condition substantially the same as the condition in which it was manufactured and sold.

35. Plaintiff agreed to initiate treatment with JARDIANCE in an effort to reduce her blood sugar. In doing so, Plaintiff relied on claims made by Defendants that JARDIANCE was safe and effective for the treatment of diabetes.

36. Instead, JARDIANCE can cause severe injuries, including diabetic ketoacidosis.

37. On or about July 29, 2015, after beginning JARDIANCE treatment, and as a direct and proximate result thereof, Plaintiff Luz Lechuga suffered diabetic ketoacidosis resulting in admission to the intensive care unit at Del Sol Medical Center in El Paso, Texas.

38. Defendants knew or should have known the risks associated with the use of JARDIANCE, including the risk of developing diabetic ketoacidosis.

39. The development of Plaintiff's injuries was preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life threatening risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of JARDIANCE. This conduct, as well as the product defects complained of herein, were substantial factors in bringing about and exacerbating Plaintiff's injuries.

40. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct and JARDIANCE's defects.

41. At all times material hereto, Defendants, by and through their agents, servants and employees, negligently, recklessly and carelessly marketed, distributed

and sold JARDIANCE without adequate instructions or warning of its serious side effects and unreasonably dangerous risks.

42. Plaintiff would not have used JARDIANCE had Defendants properly disclosed the risks associated with the drug. Thus, had Defendants properly disclosed the risks associated with JARDIANCE, Plaintiff would have avoided the risk of developing the injuries complained of herein by not ingesting JARDIANCE.

43. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking JARDIANCE.

44. As a result of Defendants' actions, Plaintiff and her prescribing physicians were unaware, and could not reasonably have known or learned through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

45. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of JARDIANCE, Plaintiff suffered severe and permanent physical and emotional injuries. Plaintiff has endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

46. Plaintiff has suffered from mental anguish from the knowledge that she may suffer life-long complications as a result of the injuries caused by JARDIANCE.

FIRST CAUSE OF ACTION
PRODUCTS LIABILITY – DESIGN DEFECT (STRICT LIABILTY)

47. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

48. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed JARDIANCE, including the JARDIANCE used by Plaintiff, which was in a defective and unreasonably dangerous condition.

49. Defendants expected JARDIANCE to reach, and it did in fact reach, Plaintiff without substantial change in the condition in which it was manufactured and sold by the Defendants.

50. At all times relevant hereto, Defendants JARDIANCE was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition and was dangerous for use by the public and in particular by Plaintiff.

51. At all times relevant to this action, JARDIANCE, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by the Defendants, was defective in design and formulation in one or more of the following particulars:

a. When placed in the stream of commerce, JARDIANCE contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the drug;

b. When placed in the stream of commerce, JARDIANCE was defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect and more dangerous that other risks associated with the treatment of diabetes;

c. JARDIANCE was insufficiently tested;

d. JARDIANCE caused harmful side effects that outweighed any potential utility;

e. Defendants were aware at the time JARDIANCE was marketed that ingestion of JARDIANCE would result in an increased risk of diabetic ketoacidosis, and other injuries;

f. JARDIANCE was subject to inadequate post-marketing surveillance; and/or

g. There were safer alternative designs and formulations that were not utilized.

52. JARDIANCE was defective, failed to perform safely, and was unreasonably dangerous when used by ordinary consumers, including Plaintiff, as intended and in a reasonably foreseeable manner.

53. JARDIANCE, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in its design or formulation, in that it was unreasonably dangerous and its foreseeable risks exceeded the alleged benefits associated with JARDIANCE's design or formulation.

54. JARDIANCE, as designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and/or distributed by Defendants, was defective in design or formulation in that it posed a greater likelihood of injury than other diabetes drugs and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

55. At all times relevant to this action, Defendants knew or had reason to know that JARDIANCE was in a defective condition and was inherently dangerous and unsafe when used in a manner instructed, provided, and/or promoted by Defendants.

56. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain supply, provide proper warnings, and otherwise ensure that JARDIANCE was not unreasonably dangerous for its normal, common, intended use, or for use in a form and manner instructed and provided by Defendants.

57. When Defendants placed JARDIANCE into the stream of commerce, they knew it would be prescribed to treat diabetes, and they marketed and promoted JARDIANCE as safe for treating diabetes.

58. Plaintiff was prescribed, purchased, and used JARDIANCE. Plaintiff used JARDIANCE for its intended purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants.

59. Neither Plaintiff nor Plaintiff's health care professionals, by exercise of reasonable care, could have discovered the defects and risks associated with JARDIANCE before Plaintiff's ingestion of JARDIANCE.

60. The harm caused by JARDIANCE far outweighed its benefit, rendering JARDIANCE more dangerous than alternative products. Defendants could have designed JARDIANCE to make it less dangerous. When Defendants designed JARDIANCE, the state of the industry's scientific knowledge was such that a less risky design was attainable.

61. At the time JARDIANCE left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the reasonably anticipated or

intended function of JARDIANCE. This was demonstrated by the existence of other diabetes medications that had a more established safety profile and a considerably lower risk profile.

62. Defendants' defective design of JARDIANCE was willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of JARDIANCE. Defendants' conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of JARDIANCE.

63. The defects in JARDIANCE were substantial and contributing factors in causing Plaintiff's injuries. But for Defendants' acts and omissions, Plaintiff would not have suffered the injuries complained of herein.

64. Due to the unreasonably dangerous condition of JARDIANCE, Defendants are liable to Plaintiff.

65. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of JARDIANCE, including Plaintiff, with knowledge of the safety problems associated with JARDIANCE, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

66. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk

of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

SECOND CAUSE OF ACTION
PRODUCTS LIABILITY – FAILURE TO WARN (STRICT LIABILTY)

67. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

68. Defendants have engaged in the business of designing, developing, researching, testing, licensing, manufacturing, packaging, labeling, promoting, marketing, selling, and/or distributing JARDIANCE. Through their conduct, Defendants knowingly and intentionally placed JARDIANCE into the stream of commerce with full knowledge that it reaches consumers, such as Plaintiff, who ingested it.

69. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released JARDIANCE into the stream of commerce. In the course of same, Defendants directly advertised, marketed, and promoted JARDIANCE to the FDA, health care professionals, Plaintiff, and other consumers, and therefore had a duty to warn of the risks associated with the use of JARDIANCE.

70. Defendants expected JARDIANCE to reach, and it did in fact reach, prescribing health care professionals and consumers, including Plaintiff and Plaintiff's health care professionals, without any substantial change in the condition of the product from when it was initially distributed by Defendants.

71. JARDIANCE, as manufactured and/or supplied by Defendants, was defective due to inadequate warnings or instructions, Defendants knew or should have known that the prudent created significant risks of serious bodily harm to consumers, as alleged herein, and they failed to adequately warn consumers and/or their health care professionals of such risks.

72. JARDIANCE was defective and unsafe such that it was unreasonably dangerous when it left the Defendants' possession and/or control, was distributed by Defendants, and ingested by Plaintiff. JARDIANCE contained warnings insufficient to alert consumers, including Plaintiff, to the dangerous risks and reactions associated with JARDIANCE, including the development of Plaintiff's injuries.

73. This defect caused serious injury to Plaintiff, who used JARDIANCE for its intended purpose and in a reasonably anticipated manner.

74. At all times herein mentioned, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take such other steps as necessary to ensure JARDIANCE did not cause users to suffer from unreasonable and dangerous risks.

75. Defendants negligently and recklessly labeled, distributed, and promoted JARDIANCE.

76. Defendants had a continuing duty to warn Plaintiff of the dangers associated with JARDIANCE.

77. Defendants, as manufacturers, sellers, or distributors of prescription drugs, are held to the knowledge of an expert in the field.

78. Plaintiff could not have discovered any defects in JARDIANCE through the exercise of reasonable care and relied upon the skill, superior knowledge, and judgment of Defendants.

79. Defendants were aware of the probable consequences of the aforesaid conduct. Despite the facts that Defendants knew or should have known that JARDIANCE caused serious injuries, they failed to exercise reasonable care to warn of the severity of the dangerous risks associated with its use. The dangerous propensities of JARDIANCE, as referenced above, were known to the Defendants, or scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the product. Such information was not known to ordinary physicians who would be expected to prescribe the drug for their patients.

80. JARDIANCE, as manufactured and/or supplied by Defendants, was unreasonably dangerous when used by consumers, including Plaintiff, in a reasonably intended manner without knowledge of this risk of serious bodily harm.

81. Each of the Defendants knew or should have known that the limited warnings disseminated with JARDIANCE were inadequate, but the Defendants failed to communicate adequate information on the dangers and safe use of JARDIANCE, taking into account the characteristics of, and the ordinary knowledge common to, physicians who would be expected to prescribe the drug. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for treatment of diabetes.

82. Defendants communicated to health care professionals information that failed to contain relevant warnings, hazards, contraindications, efficacy, side effects, and precautions, that would enable health care professionals to prescribe the drug safely for use by patients for the purposes for which it is intended. In particular, Defendants:

a. Disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with the use of JARDIANCE;

b. continued to aggressively promote JARDIANCE even after Defendants knew or should have known of the unreasonable risks from use;

c. failed to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of JARDIANCE and the comparative severity of such adverse effects;

d. failed to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with the severity of JARDIANCE's effect on acid-base balance; and

e. overwhelmed, downplayed, or otherwise suppressed, through aggressive marketing and promotion the risks associated with the use of JARDIANCE.

83. To this day, Defendants have failed to adequately and accurately warn of the true risks of injuries associated with the use of JARDIANCE.

84. Due to these deficiencies and inadequacies, JARDIANCE was unreasonably dangerous and defective as manufactured, distributed, promoted, advertised, sold, labeled, and marketed by the Defendants.

85. Had Defendants properly disclosed and disseminated the risks associated with JARDIANCE, Plaintiff would have avoided the risk of developing injuries as alleged herein.

86. The Defendants are liable to Plaintiff for injuries caused by their negligent or willful failure to provide adequate warnings or other clinically relevant information and data regarding the appropriate use of JARDIANCE and the risks associated with its use.

87. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

THIRD CAUSE OF ACTION

WILLFUL AND WANTON CONDUCT OR GROSS NEGLIGENCE

88. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

89. The wrongs done by the Defendants were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, in that the Defendants' conduct was specifically intended to cause substantial injury to Plaintiff. When viewed objectively from the Defendants' standpoint at the time of the conduct, considering the probability and magnitude of the potential harm to others, the Defendants' conduct involved an extreme degree of risk.

90. The Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to or a conscious disregard for to the rights, safety, or welfare of others. Moreover, the Defendants made material representations that were false, with actual knowledge of or reckless disregard for their falsity, with the intent that the representations be acted on by Plaintiff and her healthcare providers.

91. Plaintiff relied on the Defendants' representations and suffered injuries as a proximate result of this reliance. Plaintiff therefore asserts claims for exemplary damages.

92. Plaintiff also alleges that the acts and omissions of the Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff.

93. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and the Defendants' reckless disregard for the public safety

and welfare. The Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety of JARDIANCE. The Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of JARDIANCE, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting JARDIANCE, despite Defendants' knowledge and awareness of these serious side effects and risks.

94. The Defendants had knowledge of, and were in possession of evidence demonstrating that JARDIANCE caused serious side effects. Notwithstanding their knowledge, the Defendants continued to market JARDIANCE by providing false and misleading information with regard to JARDIANCE's safety to regulatory agencies, the medical community, and consumers of JARDIANCE.

95. Although Defendants knew or recklessly disregarded the fact that JARDIANCE causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and distribute JARDIANCE to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating diabetes.

96. Defendants failed to provide adequate warnings that would have dissuaded health care professionals from prescribing JARDIANCE and consumers from purchasing and ingesting JARDIANCE, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming JARDIANCE.

97. Defendants knew of the defective nature of JARDIANCE as set forth herein, but continued to design, manufacture, market, distribute, sell, and/or promote JARDIANCE to maximize sales and profits at the expense of the health and safety of the

public, including Plaintiff, in a conscious, reckless, or negligent disregard of the foreseeable harm caused JARDIANCE.

98. Defendants' acts, conduct, and omissions were willful and malicious. Defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiff and other users of JARDIANCE and for the primary purpose of increasing Defendants' profits from the sale and distribution of JARDIANCE. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all Defendants in an amount appropriate to punish and make an example out of each.

99. Prior to the manufacture, sale, and distribution of JARDIANCE, Defendants knew that JARDIANCE was, and is, in a defective condition and knew that those who were prescribed JARDIANCE would experience and did experience severe physical, mental, and emotional injuries. Further, each defendant, through their officers, directors, managers, and agents, knew that JARDIANCE presented a substantial and unreasonable risk of harm to the public, including Plaintiff. As such, Defendants unreasonably subjected consumers of JARDIANCE, including Plaintiff, to risk of serious injury or death.

100. Despite their knowledge Defendants, acting through their officers, directors and managing agents, for the purpose of enhancing the Defendants' profits, knowingly and deliberately failed to remedy the known defects in JARDIANCE and failed to adequately warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects. Defendants and their respective agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of JARDIANCE knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

101. Defendants' conduct was committed with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

FOURTH CAUSE OF ACTION
NEGLIGENCE

102. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

103. Defendants directly or indirectly caused JARDIANCE to be sold, distributed, packaged, labeled, marketed, promoted, and/or used by Plaintiff.

104. The Defendants owed Plaintiff and other consumers a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling JARDIANCE, including the duty to take all reasonable steps necessary to ensure the product was not unreasonably dangerous to its consumers and users, and to warn Plaintiff and other consumers of the dangers associated with JARDIANCE.

105. At all times material hereto, Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers of JARDIANCE.

106. Defendants had a duty to disclose to health care professionals the causal relationship or association of JARDIANCE to the development of Plaintiff's injuries.

107. Defendants' duty of care owed to consumers, health care professionals, and patients included providing accurate information concerning: (1) the clinical safety and effectiveness profiles of JARDIANCE, and (2) appropriate, complete, and accurate warnings concerning the adverse effects of JARDIANCE, including the injuries suffered by Plaintiff.

108. During the time that Defendants designed, manufactured, packaged, labeled, promoted, distributed, and/or sold JARDIANCE, Defendants knew, or in the exercise of reasonable care should have known that their product was defective, dangerous, and otherwise harmful to Plaintiff.

109. Defendants knew or in the exercise of reasonable care should have known, that the use of JARDIANCE could cause or be associated with Plaintiff's injuries and thus created a dangerous and unreasonable risk of injury to users if the products.

110. Defendants knew that many health care professionals were prescribing JARDIANCE, and that many patients developed serious side effects including but not limited to diabetic ketoacidosis.

111. Defendants breached their duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, marketing, supplying, promotion, advertisement, packaging, sale, testing, quality assurance, quality control, and distribution of JARDIANCE in interstate commerce, in that Defendants knew and had reason to know that consumers' use and ingestion of JARDIANCE created a significant risk of suffering unreasonably dangerous health related side effects, including Plaintiff's injuries, and failed to prevent or adequately warn of the severity of these risks and injuries.

112. Defendants were further negligent in that they manufactured and produced a defective product containing *empagliflozin*, knew and were aware of the

defects inherent in the product, failed to act in a reasonably prudent manner in designing, testing, and marketing the product, and failed to provide adequate warnings of the product's defects and risks.

113. The Defendant's failed to exercise due care under the circumstances, and their negligence includes the following acts and omissions:

a. failing to properly and thoroughly test JARDIANCE before releasing the drug to market;

b. failing to properly and thoroughly analyze the data resulting from the premarketing tests of JARDIANCE;

c. failing to conduct sufficient post-market testing and surveillance of JARDIANCE;

d. designing, manufacturing, marketing, advertising, distributing, and selling JARDIANCE to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of JARDIANCE and without proper instructions to avoid foreseeable harm;

e. failing to accompany their product with proper or adequate warnings or labeling regarding adverse side effects and health risks associated with the use of JARDIANCE and the comparative severity of such adverse effects;

f. failing to provide warnings, instructions or other information that accurately reflected the symptoms, scope, and severity of the side effects and health risks, including but not limited to those associated with the severity of JARDIANCE's effect and acid-base balance;

g. failing to exercise due care when advertising and promoting JARDIANCE; and

h. negligently continuing to manufacture, market, advertise, and distribute JARDIANCE after the Defendants knew or should have known of its adverse effects.

114. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of JARDIANCE.

115. Plaintiff did not know the nature and extent of the injuries that could result from ingestion and use of JARDIANCE.

116. Defendants' negligence was the proximate cause of the injuries, harm, and economic losses that Plaintiff suffered, and will continue to suffer, as described herein.

117. Defendants' conduct, as described above, was reckless. Defendants' actions and inaction risked the lives of consumers and users of their products, including Plaintiff.

118. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs

herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

FIFTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

119. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

120. At all times material hereto, Defendants engaged in the business of testing, developing, designing, manufacturing, packaging, labeling, marketing, promoting, selling, and/or distributing JARDIANCE, which is unreasonably dangerous and defective, thereby placing JARDIANCE into the stream of commerce.

121. Defendants expressly represented to Plaintiff, other consumers, Plaintiff's physicians, and the medical community, by and through statements made and written materials disseminated by Defendants or their authorized agents or sales representatives, that JARDIANCE:

a. was safe and fit for its intended purposes;

b. was of merchantable quality;

c. did not produce any dangerous side effects; and

d. had been adequately tested and found to be safe and effective for the treatment of diabetes.

122. These express representations include incomplete prescribing information that purports, but fails, to include the true risks associated with the use of JARDIANCE.

In fact, Defendants knew or should have known that the risks identified in JARDIANCE's prescribing information and package inserts do not accurately set forth the drug's true risks. Despite this, Defendants expressly warranted JARDIANCE as safe and effective for use.

123. Defendants advertised, labeled, marketed, and promoted JARDIANCE, representing the quality to health care professionals, Plaintiff, and the public in such a way as to induce JARDIANCE's purchase or use, thereby making an express warranty that JARDIANCE would conform to the representations. More specifically, the prescribing information for JARDIANCE did not and does not contain adequate information about the true risks of developing the injuries complained of herein.

124. Despite this, Defendants expressly represented that JARDIANCE was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat diabetes. Portions of the prescribing information relied upon by Plaintiff and Plaintiff's health care professionals, including the "Warnings and Precautions" section, purport to expressly include the risks associated with the use of JARDIANCE, but those risks are neither accurate nor adequately set forth.

125. The representations about JARDIANCE contained or constituted affirmations of fact or promises made by the sell to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

126. JARDIANCE does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries. Therefore, Defendants breached the aforementioned warranties.

127. At all times relevant, JARDIANCE did not perform safely and as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

128. Neither Plaintiff nor Plaintiff's prescribing health care professionals had knowledge of the falsity or incompleteness of the Defendants' statements and representations concerning JARDIANCE.

129. Plaintiff, other consumers, Plaintiff's physicians, and the medical community justifiably and detrimentally relied upon Defendants' express warranties when prescribing and ingesting JARDIANCE.

130. Had the prescribing information for JARDIANCE accurately set forth the true risks associated with the use of such product, including Plaintiff's injuries, rather than expressly excluding such information and warranting that the product was safe for its intended use, Plaintiff could have avoided the injuries complained of herein.

131. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems

just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

SIXTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

132. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

133. Defendants manufactured, distributed, advertised, promoted, and sold JARDIANCE.

134. At all relevant times, Defendants knew of the use for which JARDIANCE was intended, and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

135. Defendants were aware that consumers, including Plaintiff, would use JARDIANCE for treatment of type 2 diabetes and for other purposes, including but not limited to weight loss, and reduced blood pressure.

136. JARDIANCE was neither safe for its intended use nor of merchantable quality, as impliedly warranted by Defendants, in that JARDIANCE has dangerous propensities when used as intended and can cause serious injuries, including diabetic ketoacidosis, stroke, heart attack, and severe kidney damage.

137. At all relevant times, Defendants intended that JARDIANCE be used in the manner used by Plaintiff, and Defendants impliedly warranted it to be of merchantable quality, safe, and fit for such use, despite the fact that JARDIANCE was not adequately tested.

138. Defendants were aware that consumers, including Plaintiff, would use JARDIANCE as marketed by Defendants. As such, Plaintiff was a foreseeable user of JARDIANCE.

139. Upon information and belief, Plaintiff and/or Plaintiff's health care professionals were at all relevant times in privity with Defendants.

140. JARDIANCE was dangerous and defective when Defendants placed it into the stream of commerce because of its propensity to cause Plaintiff's injuries.

141. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Defendants to sell JARDIANCE only if it was indeed of merchantable quality and safe and fit for its intended use.

142. Defendants breached their implied warranty to consumers, including Plaintiff. JARDIANCE was not of merchantable quality, nor was it safe and fit for its intended use.

143. Plaintiff and Plaintiff's physicians reasonably relied upon Defendants' implied warranty for JARDIANCE when prescribing and ingesting JARDIANCE.

144. Plaintiff's use of JARDIANCE was as prescribed and in a foreseeable manner as intended, recommended, promoted, and marketed by Defendants.

145. JARDIANCE was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendants.

146. Defendants breached the warranties of merchantability and fitness for its particular purpose because JARDIANCE was unduly dangerous and caused undue injuries, including Plaintiff's injuries.

147. The harm caused by JARDIANCE far outweighed its alleged benefit, rendering JARDIANCE more dangerous than an ordinary consumer or health care professional would expect and more dangerous than alternative products.

148. Neither Plaintiff nor Plaintiff's health care professionals reasonably could have discovered or known of the risk of serious injury and death associated with JARDIANCE.

149. Defendants' breach of these implied warranties caused Plaintiff's injuries.

150. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

SEVENTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

151. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

152. Defendants made fraudulent misrepresentations with respect to JARDIANCE in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that JARDIANCE had been tested and found to be safe and effective for the treatment of diabetes; and

b. Upon information and belief, Defendants represented that JARDIANCE was safer than other alternative medications.

153. Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligation to provide truthful representations regarding the safety and risk of JARDIANCE to Plaintiff, other consumers, Plaintiff's physicians, and the medical community.

154. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff and Plaintiff's physicians, rely upon them.

155. Defendants' representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, Plaintiff's physicians, and the medical community to induce and encourage the sale of JARDIANCE.

156. Plaintiff, Plaintiff's doctors, and others relied upon these representations.

157. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur

medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

EIGHTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

158. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

159. Defendants owed a duty in all of their undertakings, including the dissemination of information concerning JARDIANCE, to exercise reasonable care to ensure they did not create unreasonable risks of personal injury to others.

160. Defendants disseminated to health care professionals and consumers – through published labels, marketing materials, and otherwise – information that misrepresented the properties and effects of JARDIANCE with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe or ingest JARDIANCE.

161. Defendants, as the designers, manufacturers, sellers, promoters, and/or distributors of JARDIANCE, knew or reasonably should have known that health care

professionals and consumers of JARDIANCE rely on information disseminated and marketed to them regarding the product when weighing the potential benefits and potential risks of prescribing or ingesting JARDIANCE.

162. Defendants failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of JARDIANCE were accurate, complete, and not misleading. As a result, Defendants disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiff.

163. Defendants, as designers, manufacturers, sellers, promoters, and/or distributors of JARDIANCE, knew or reasonably should have known that health care professionals would write prescriptions for JARDIANCE in reliance on the information disseminated by Defendants, and that the patients receiving prescriptions for JARDIANCE would be placed in peril of developing serious and potentially life threatening injuries if the information disseminated by Defendants and relied upon was materially inaccurate, misleading, or otherwise false.

164. From the time JARDIANCE was first tested, studied, researched, evaluated, endorsed, manufactured, marketed, and distributed, and up to the present, Defendants failed to disclose material facts regarding the safety of JARDIANCE. Defendants made material misrepresentations to Plaintiff, Plaintiff's health care professionals, the healthcare community, and the general public, including:

a. Stating that JARDIANCE had been tested and found to be safe and effective for the treatment of diabetes;

b. Concealing, misrepresenting, actively downplaying the severe and life threatening risks of harm to users of JARDIANCE, when compared to comparable or superior alternative pharmaceutical therapies; and

c. Misrepresenting JARDIANCE's risk of unreasonable, dangerous, adverse side effects.

165. Defendants made the foregoing representations without any reasonable ground for believing them to be true.

166. These representations were made directly by Defendants, their sales representative, and other authorized agents, and in publications and other written materials directed to health care professionals, medical patients, and the public.

167. Defendants made these representations with the intent to induce reliance thereon, and to encourage prescription, purchase, and use of JARDIANCE.

168. Defendants had a duty to accurately and truthfully represent to medical professionals and consumers, including Plaintiff, the truth regarding Defendants' claims that JARDIANCE had been tested and found to be safe and effective for treating diabetes.

169. The misrepresentations made by Defendants, in fact were false and known by Defendants to be false at the time the misrepresentations were made.

170. Defendants failed to exercise ordinary care in making their representations concerning JARDIANCE in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce of JARDIANCE.

171. Defendants engaged in a nationwide marketing campaign, over-promoting JARDIANCE in written marketing literature, in written product packaging, and in direct-to-consumer advertising via written and internet advertisements and television commercial ads. Defendants' over-promotion was undertaken by touting the

safety and efficacy of JARDIANCE while concealing, misrepresenting, and actively downplaying the serious, severe, and life-threatening risks of harm to users of JARDIANCE, when compared to comparable or superior alternative drug therapies. Defendants negligently misrepresented JARDIANCE's risk of unreasonable and dangerous adverse side effects.

172. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of JARDIANCE, including Plaintiff. Defendants had knowledge of the safety problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

173. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

NINTH CAUSE OF ACTION
NEGLIGENT DESIGN

174. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

175. At all relevant times, Defendants owed a duty to consumers, including Plaintiff and Plaintiff's health care professionals, to exercise reasonable care in the design of JARDIANCE.

176. Defendants negligently and carelessly breached this duty of care to Plaintiff because JARDIANCE was and is unreasonably defective in design as follows:

a. JARDIANCE unreasonably increased the risk of developing Plaintiff's injuries as complained of herein;

b. JARDIANCE was more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with like products;

c. JARDIANCE contained insufficient, incorrect, and defective warnings in that it failed to alert health care professionals and users including Plaintiff, of the severity of the risks of adverse effects;

d. JARDIANCE was not safe for its intended use;

e. JARDIANCE was not adequately tested; and/or

f. JARDIANCE's risks exceeded any benefit of the drug.

177. JARDIANCE was expected to, and did, reach the intended consumers, handlers and persons coming into contact with the drug without substantial change in the condition in which it was researched, tested, developed, designed, licensed, manufactured, packaged, labeled, distributed, sold, and marketed by Defendants.

178. At all times relevant hereto, JARDIANCE was manufactured, designed and labeled in an unsafe, defective and inherently dangerous condition, which was dangerous for use by the public and in particular by Plaintiff.

179. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, common intended use.

180. Plaintiff used JARDIANCE for its intended purposes and in a manner normally intended: primarily to treat diabetes.

181. The harm caused by JARDIANCE far outweighed the benefits, rendering JARDIANCE more dangerous and less effective than an ordinary consumer or health care professionals would expect and more dangerous than alternative products. Defendants could have designed JARDIANCE to make it less dangerous. When Defendants manufactured JARDIANCE, the state of the industry's scientific knowledge was such that a less risky design was attainable.

182. At the time JARDIANCE left Defendants' control, there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of JARDIANCE. This was demonstrated by the existence of other diabetes medications that had a more established safety profile and a considerably lower risk profile.

183. Plaintiff could not have, in the reasonable exercise of care, discovered the defects of JARDIANCE and perceived its dangers.

184. The defects in JARDIANCE were substantial contributing factors in causing Plaintiff's injuries. But for Defendants' acts and omissions, Plaintiff would not have suffered the injuries complained of herein.

185. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and

other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

TENTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT

186. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

187. Throughout the relevant time period, Defendants knew that JARDIANCE was defective and unreasonably unsafe for its intended purpose, and intentionally and willfully failed to disclose and/or suppressed information regarding the true nature of the risks of use of JARDIANCE.

188. Defendants fraudulently concealed information with respect to JARDIANCE in the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submission that JARDIANCE was safe and fraudulently withheld and concealed information about the severity of the substantial risks of using JARDIANCE; and

b. Upon information and belief, Defendants represented that JARDIANCE was safer than other alternative medications and fraudulently concealed information which demonstrated that JARDIANCE was not safer than alternatives available on the market.

189. Defendants were under a duty to Plaintiff to disclose and warn of the defective and dangerous nature of JARDIANCE because:

a. Defendants had sole access to material facts concerning, and unique and special expertise regarding, the dangers and unreasonable risks of JARDIANCE;

b. Defendants knowingly made false claims and omitted important information about the safety and quality of JARDIANCE in the documents and marketing materials Defendants provided to physicians and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective and dangerous nature of JARDIANCE from Plaintiff.

190. As the designers, manufacturers, sellers, promoters, and/or distributors of JARDIANCE, Defendants had unique knowledge and special expertise regarding JARDIANCE. This placed them in a position of superiority and influence over Plaintiff and her healthcare providers. As such, Plaintiff and Plaintiff's health care providers

reasonably placed their trust and confidence in Defendants and in the information disseminated by Defendants.

191. The facts concealed or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase or use JARDIANCE.

192. The concealment and/or non-disclosure of information by Defendants about the severity of the risks caused by JARDIANCE was intentional, and the representations made by Defendants were known by them to be false.

193. The concealment of information and the misrepresentations about JARDIANCE were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them so that Plaintiff would request and purchase JARDIANCE and Plaintiff's health care providers would prescribe and recommend JARDIANCE.

194. Plaintiff, Plaintiff's doctors, and others reasonably relied on Defendants' representations and were unaware of the substantial risk posed by JARDIANCE.

195. Had Defendants not concealed or suppressed information regarding the severity of the risks of JARDIANCE, Plaintiff and Plaintiff's physicians would not have prescribed or ingested the drug.

196. Defendants, by concealment or other action, intentionally prevented Plaintiff and her health care professionals from acquiring material information regarding the lack of safety of JARDIANCE, thereby preventing Plaintiff from discovering the truth. As such, Defendants are liable for fraudulent concealment.

197. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to

require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

ELEVENTH CAUSE OF ACTION
FRAUD

198. Plaintiff repeats, reiterates and re-alleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

199. Defendants intentionally, willfully, and knowingly, fraudulently misrepresented to Plaintiff, Plaintiff's prescribing health care professionals, the health care industry and consumers that JARDIANCE had been adequately tested in clinical trials and was found to be safe and effective as a diabetes treatment.

200. Defendants knew or should have known at the time they made their fraudulent misrepresentations that their material misrepresentations and omissions were false regarding the dangers and risks of adverse health events associated with the use of JARDIANCE. Defendants made their fraudulent misrepresentations willfully,

wantonly, and with reckless disregard and depraved indifference for the safety and well-being of the users of JARDIANCE, such as Plaintiff.

201. Defendants' fraudulent misrepresentations were made with the intent of defrauding and deceiving the health care industry and consumers, including Plaintiff and her prescribing health care professionals, so as to induce them to recommend, prescribe, disperse, or purchase JARDIANCE, despite the risk of severe life threatening injuries, which Defendants knew were caused by the product.

202. The Defendants fraudulently and intentionally concealed material information, as aforesaid, Defendants knew that JARDIANCE was defective and unreasonably unsafe for its intended purpose and intentionally failed to disclose information regarding the true nature of the product's risk.

203. Defendants fraudulently and intentionally failed to disclose and warn of the severity of the injuries described herein, which were known by Defendants to result from use of JARDIANCE.

204. Defendants fraudulently and intentionally suppressed information about the severity of the risks of injuries associated with JARDIANCE from physicians and patients, including Plaintiff and her prescribing physicians, used sales and marketing documents that contained information contrary to Defendants' internally held knowledge regarding the aforesaid risks and injuries, and overstated the efficacy and safety of JARDIANCE. For example:

a. JARDIANCE was not as safe and effective as other diabetes drugs given its intended use;

b. Ingestion of JARDIANCE does not result in a safe and more effective method of diabetes treatment than other available treatments;

c. The risks of harm associated with the use of JARDIANCE was greater than the risks of harm associated with other forms of diabetes drug therapies;

d. The risk of adverse events with JARDIANCE was not adequately tested and was known by Defendants, but Defendants knowingly failed to adequately test the product;

e. Defendants knew that the risks of harm associated with the use of JARDIANCE was greater than the risks of harm associated with other forms of diabetes drug therapies, yet knowingly made material misrepresentations and omissions of fact on which Plaintiff relied when ingesting JARDIANCE;

f. The limited clinical testing revealed that JARDIANCE had an unreasonably high risk of injury, including Plaintiff's injuries, above and beyond those associated with other diabetes drug therapies;

g. Defendants intentionally and knowingly failed to disclose and concealed the adverse events discovered in the clinical studies and trial results;

h. Defendants had knowledge of the dangers involved with the use of JARDIANCE, which dangers were greater than those associated with other diabetes drug therapies;

i. Defendants intentionally and knowingly failed to disclose that patients using JARDIANCE could suffer diabetic ketoacidosis; and/or

j. JARDIANCE was defective, and caused dangerous and adverse side effects, including the specific injuries described herein.

205. Defendants had access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of

dangerous injuries and damages to persons who ingest JARDIANCE, information that was not publicly disseminated or made available, but instead was actively suppressed by Defendants.

206. Defendants' intentional concealment and omissions of material facts concerning the safety of JARDIANCE was made with purposeful, willful, wanton, fraudulent, and reckless disregard for the health and safety of Plaintiff, and with reckless intent to mislead, so as to cause Plaintiff's prescribing physicians to purchase, prescribe, and/or dispense JARDIANCE, and to cause Plaintiff to rely on Defendants' fraudulent misrepresentations that JARDIANCE was a safe and effective diabetes drug therapy.

207. At the time Plaintiff purchased and used JARDIANCE, Plaintiff was unaware that Defendants had made misrepresentations and omissions, and instead Plaintiff reasonably believed Defendants' representations to constitute a true, complete, and accurate portrayal of JARDIANCE's safety and efficacy.

208. Defendants knew and had reason to know that JARDIANCE could and would cause serious personal injury to the users of the product, and that the product was inherently dangerous in a manner that exceeded any purported warnings given by Defendants.

209. In reliance on Defendants' false and fraudulent misrepresentations, Plaintiff was induced to use and in fact used JARDIANCE, thereby sustaining injuries and damages. Defendants knew and had reason to know that Plaintiff and her health care professionals did not have the ability to determine the true facts intentionally concealed and suppressed by Defendants, and that Plaintiff and her health care professionals would not have prescribed and ingested JARDIANCE if the true facts regarding the drug had not been concealed by Defendants.

210. During the marketing and promotion of JARDIANCE to health care professionals, neither Defendants nor the co-promoters who were dealing JARDIANCE on Defendants' behalf, warned health care professionals, including Plaintiff's prescribing health care professional, that JARDIANCE caused or increased the risk of harm of diabetic ketoacidosis.

211. Plaintiff reasonably relied upon Defendants' misrepresentations, where knowledge of the concealed facts was crucial to understanding the true dangers inherent in the use of JARDIANCE.

212. Defendants willfully, wrongfully, and intentionally distributed false information, assuring Plaintiff, the public, Plaintiff's health care professionals, and the health care industry that JARDIANCE was safe for use as a means of diabetes treatment. Upon information and belief, Defendants intentionally omitted, concealed, and suppressed the true results of Defendants' clinical tests and research.

213. Defendants' conduct was intentional and reckless. Defendants risked the lives of consumers and users of JARDIANCE, including Plaintiff. Defendants knew of JARDIANCE's safety problems, and suppressed this knowledge from the general public. Defendants' intentional and reckless conduct warrants an award of punitive damages.

214. As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered diabetic ketoacidosis and other related health complications. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs

include physician care, monitoring and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendant, and each of them, individually, jointly, and severally, as follows:

1. Compensatory damages in excess of the jurisdictional amount, including but not limited to, non-economic damages in excess of $75,000.

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Pain and suffering;

4. Non-economic damages for an increased risk of future complications as a direct result of plaintiff's injury;

5. Punitive damages;

6. Prejudgment interest at the highest lawful rate allowed by law;

7. Interest on the judgment at the highest legal rate from the date of judgment until collected;

8. Attorneys' fees, expenses, and costs of this action; and

9. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiff demands trial by jury on all issues within this Petition.

Dated:July 28, 2017

/s/ *Shalimar Wallis*
Shalimar Wallis
Watts Guerra, LLP
4 Dominion Drive, Bldg 3
Suite 100
San Antonio, TX 78257
Phone: (210) 447-0500
Fax: (210) 447-0501
swallis@wattsguerra.com

Levi M. Plesset
(to be admitted Pro Hac Vice)
(CA State Bar No. 296039)
MILSTEIN,
JACKSON, FAIRCHILD
& WADE, LLP
10250 Constellation Blvd.
Suite 1400
Los Angeles, CA 90094
Phone (310) 396-9600
Facsimile (310) 396-9635
lplesset@mjfwlaw.com